

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEXTREMITY SOLUTIONS, INC.,
ZIMMER BIOMET HOLDINGS, INC., and ZIMMER INC.,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

IPR2022-00802
Patent 8,303,589 B2

Before JEFFREY N. FREDMAN, JAMES A. WORTH, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Nextremity Solutions, Inc., Zimmer Biomet Holdings, Inc., and Zimmer Inc. (“Petitioner”), on April 5, 2022, filed a Petition to institute *inter partes* review of claim 59 of U.S. Patent No. 8,303,589 B2 (Ex. 1001, “the ’589 patent”). Paper 1 (“Pet.” or “Petition”). Extremity Medical LLC (“Patent Owner”) did not file a Preliminary Response. We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

A decision to institute under § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). In addition, if the Board institutes trial, it will “institute on all grounds in the petition.” PTAB Consolidated Trial Practice Guide, 5–6 (Nov. 2019); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”).

Having considered the arguments and evidence presented in the Petition, for the reasons described below, we institute *inter partes* review.

II. REAL PARTIES-IN-INTEREST

Petitioner identifies Nextremity Solutions, Inc., Zimmer Biomet Holdings, Inc., and Zimmer Inc. as the real parties-in-interest. Pet. 4. Patent Owner identifies Extremity Medical LLC as the real party-in-interest. Paper 6.

III. RELATED MATTERS

The Petition states the '589 patent is “the subject of a patent infringement lawsuit brought by the assignee of the '589 patent, Extremity Medical, LLC. (See *Extremity Medical, LLC v. Nextremity Solutions, Inc., Zimmer Biomet Holdings, Inc. and Zimmer, Inc.*, U.S. District Court for the District of Delaware, Civil Action No. 1:22-cv-00239-VAC).” Pet. 4.

IV. THE '589 PATENT

The '589 patent issued Nov. 6, 2012, from an application filed June 23, 2009. Ex. 1001, codes (45), (22). The '589 patent claims the priority benefit of a provisional application filed June 24, 2008. *Id.*, code (60).

As background, the '589 patent explains that: “Orthopedic implant devices . . . are often used to repair or reconstruct bones and joints affected by trauma, degeneration, deformity and disease, such as Charcot arthropathy caused by diabetes in some patients.” Ex. 1001, 1:22–26. The '589 patent teaches “Charcot arthropathy (or Charcot foot) . . . causes bony fragmentation, dislocation, and fractures that eventually progresses to foot deformity, bony prominences, ulceration and instability of the foot.” *Id.* at 1:26–31. The '589 patent teaches “[s]urgical treatments include orthopedic fixation devices that fixate the bones in order to fuse them into a stable mass.” *Id.* at 1:38–40.

The '589 patent teaches “[v]arious implants have been utilized for surgical treatment, including bone screws. While these devices allow fixation and promote fusion, they do not deliver restoration of the arch in a Charcot foot.” Ex. 1001, 2:43–46. The '589 patent teaches an “object of the present invention is to provide a method for restoring the arch of the foot by delivering a fixator that can be coupled in a patient’s foot.” *Id.* at 2:11–13.

Figure 1 of the '589 patent provides “a perspective view of a fixation system according to a preferred embodiment of the present invention.” Ex. 1001, 3:7–8.

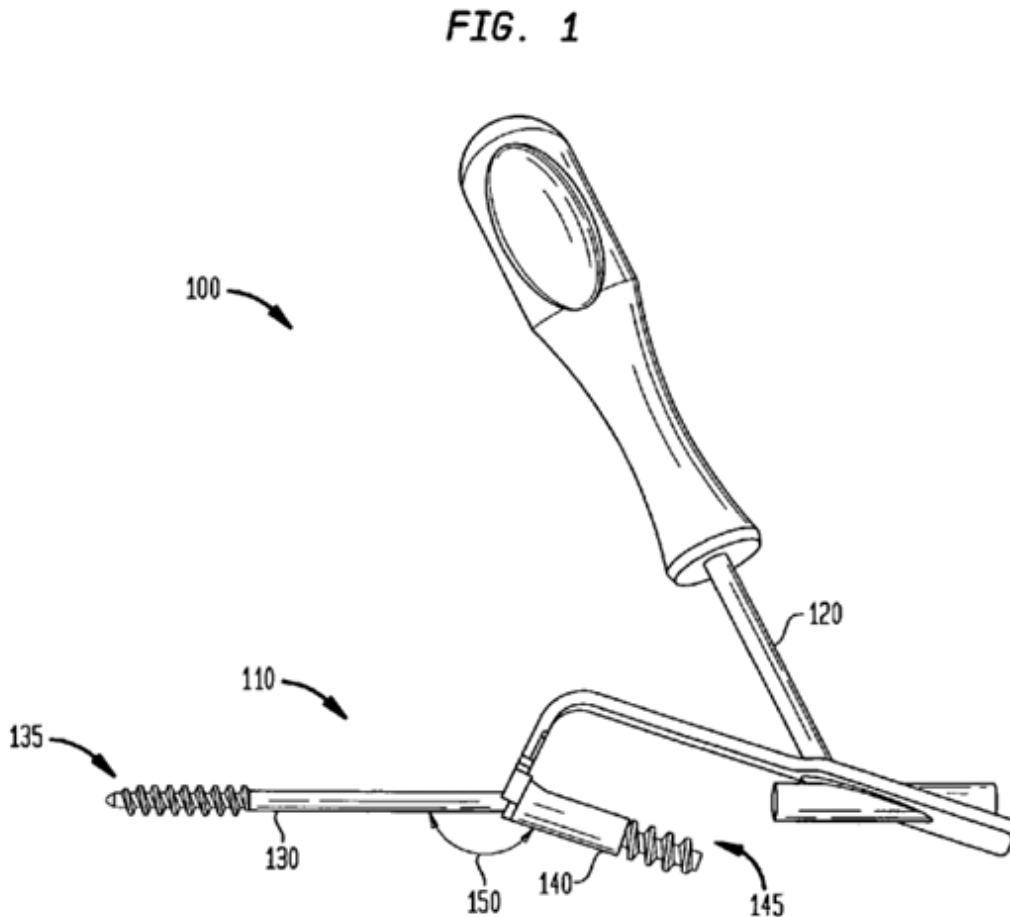


Figure 1 shows

a fixation system **100** which is made in accordance with the teachings of the preferred embodiment of the invention. As shown, the fixation system **100** includes an intramedullary fixation assembly **110**, comprising a proximal screw member **130** and a distal member **140**. Proximal screw member **130** is provided on proximal end **135** of assembly **110** and is coupled to a distal member **140** that is provided on the distal end **145** of the fixation assembly **110**. Also, proximal screw member **130** makes a fixed angle **150** with distal member **140** and this angle **150** determines the angle for arch restoration. Moreover, fixation

system **100** includes instrument **120** that is utilized to couple intramedullary fixation assembly **110** to the bones, in one non-limiting example, in the mid-foot region.

Ex. 1001, 3:50–63.

Figure 3A of the '589 patent “is a perspective view of a distal member used in the fixation system.” Ex. 1001, 3:12–13.

FIG. 3A

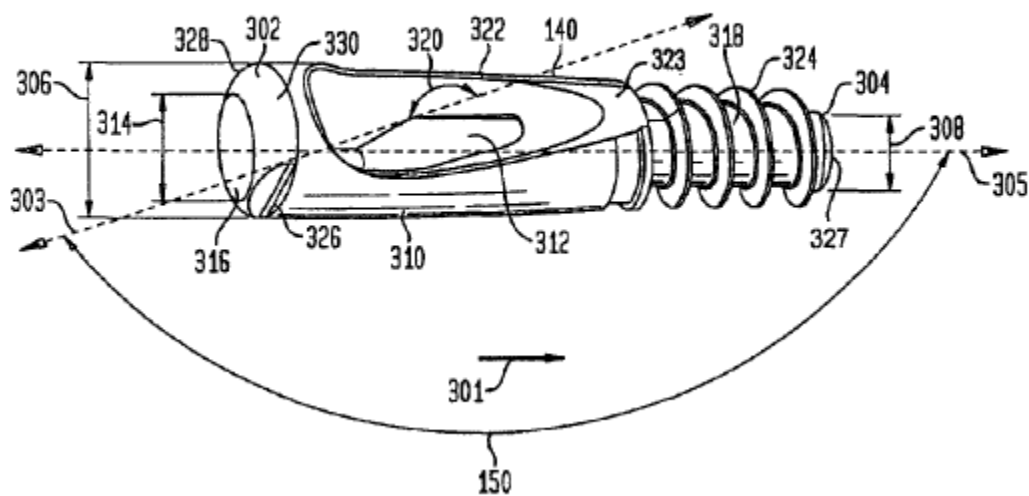


Figure 3A shows

distal member **140** of the preferred embodiment is generally tubular in shape and tapers from a first end **302** to a second end **304** . . . First end **302** has a plurality of substantially similar grooves **326** and **328**, which form an “L-shape” with surface **330** of end **302**. Grooves **326** and **328** are provided to receive instrument **120** of fixation system **100**.

Ex. 1001, 2:49 to 3:5.

V. ILLUSTRATIVE CLAIM

The '589 patent includes a number of claims, but only independent claim 59 is challenged here. Claim 59 reads:

59. A fixation system for compressing bone, comprising:
a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis;
a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis; and
an instrument adapted for coupling said first screw member to said second member;
wherein said second longitudinal axis and said bore axis define an angle,
wherein said first screw member is adapted for coupling to said second member at said angle,
wherein each of said first screw member and said second member is adapted for residing substantially within at least one bone,
and
wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument.

Ex. 1001, 12:29–47.

VI. PROSECUTION HISTORY

After an election requirement (Ex. 1005, 102¹), the Examiner initially rejected the claims in a non-final action on grounds of obviousness-type double patenting, of anticipation by Chang (Ex. 1006), and of obviousness over Chang, combined with Culbert² and Cresina.³ Ex. 1005, 65–81. The Examiner also identified some claims as objected for being dependent on a rejected base claim, but allowable if rewritten in independent form. *Id.* at 80. The Applicant responded by cancelling the rejected claims and rewriting

¹ These page numbers refer to the page numbers added to the exhibit copy, not the original pagination.

² Culbert et. al., U.S. Patent Publication 2009/0149857, published June 11, 2009.

³ Cresina et al., U.S. Patent Publication 2009/0099571, published April 16, 2009.

the objected claims into independent form or to depend from such claims.

Id. at 58–59. The Examiner then allowed the application, stating

no reference or reasonable combination thereof could be found which disclose or suggest an instrument or method of compressing bone with a second member with first and second circumferentially spaced recesses adapted for coupling to an instrument and wherein the first and second recesses are disposed a[t] the second end of the second member.

Id. at 29.

VII. ASSERTED GROUNDS

Petitioner asserts that claim 59 is unpatentable based on the following grounds:

| Claim(s) Challenged | 35 U.S.C. § | Reference(s) |
|----------------------------|--------------------|------------------------|
| 59 | 102(b) | Brumfield ⁴ |
| 59 | 102(b) | Marcus ⁵ |
| 59 | 102(b) | Chandran ⁶ |

Petitioner also relies on the declaration of Mike Sherman, in support of the asserted grounds. Ex. 1007.

VIII. LEVEL OF ORDINARY SKILL IN THE ART

The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

While the Petition does not address the definition of a person of ordinary skill in the art (“POSA” or “POSITA”) at the time of the invention, Petitioner’s expert, Dr. Sherman, states

⁴ Brumfield, D., U.S. Patent 4,827,917, issued May 9, 1989 (Ex. 1002).

⁵ Marcus, R., U.S. Patent 4,622,959, issued Nov. 18, 1986 (Ex. 1003).

⁶ Chandran, R., US 6,579,293 B1, issued June 17, 2003 (Ex. 1004).

a person of ordinary skill in the art (“POSA”) would have a bachelor’s degree in biomedical and/or mechanical engineering or similar training and would have at least five years of experience with the methods, processes and implant devices used to correct deformities in bone, stabilize fractures or fuse joints (arthrodesis).

Ex. 1007 ¶ 21. At this stage in the proceeding and absent an alternate position, we accept this level of ordinary skill in the art.

IX. CLAIM CONSTRUCTION

We interpret claim terms using “the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2020). Thus, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citations omitted) (en banc).

Here, we construe only those claim terms that require analysis to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy’”).

Petitioner asserts the “portion of the preamble reciting ‘for compressing bone’ is not limiting to the claim. The phrase ‘for compressing bone’ merely identifies an intended use.” Pet. 20. On the current record, without the benefit of Patent Owner’s views, we agree with Petitioner that

“the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). Therefore, we agree the limitation “for compressing bone” does not impose a structural limitation on claim 59.

Petitioner asserts that the terms “screw member,” “bore,” “recesses,” and “coupling” “warrant construction based on their ordinary and customary meaning to a person of ordinary skill in the art and in light of the specification and prosecution history.” Pet. 24–25. As there is no dispute regarding these terms on the current record, we need not construe these terms at this time.

Any final written decision entered in this case may include final claim constructions that differ from the preliminary understanding of the claims set forth below, or from any discussion of claim scope provided in our analysis below. Any final claim constructions will be based on the full trial record.

X. ANALYSIS

A. Introduction

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

“Determining whether claims are anticipated involves a two-step analysis. The first step involves construction of the claims of the patent at issue. Claim construction is a question of law reviewed de novo.” *In re Aoyama*, 656 F.3d 1293, 1296 (Fed.Cir.2011). “The second step [of an anticipation analysis] involves comparing the claims to the prior art. Anticipation is a question of fact reviewed for substantial evidence.” *In re Aoyama*, 656 F.3d at 1296. “A prior art reference anticipates a patent claim under 35 U.S.C. § 102(b) if it discloses every claim limitation.” *In re Montgomery*, 677 F.3d 1375, 1379 (Fed. Cir. 2012). A reference may anticipate inherently if a claim limitation that is not expressly disclosed “is necessarily present, or inherent, in the single anticipating reference.” *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1337 (Fed. Cir. 2010).

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a reasonable likelihood of success at trial.

B. Overview of the Asserted Prior Art

1. *Brumfield (Ex. 1002)*

Brumfield is a U.S. patent that teaches a devices for treating femoral fractures, specifically teaching “[i]f there is a femoral neck fracture the compression of lag screw **50** functions like a compression screw assembly to reduce the fracture.” Ex. 1002, 6:57–59. Figure 6 of Brumfield teaches lag screw 50 shown below:

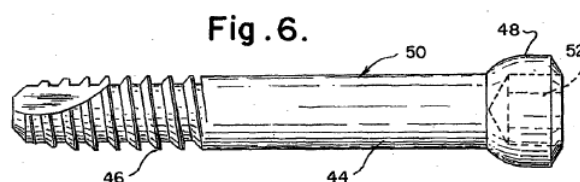
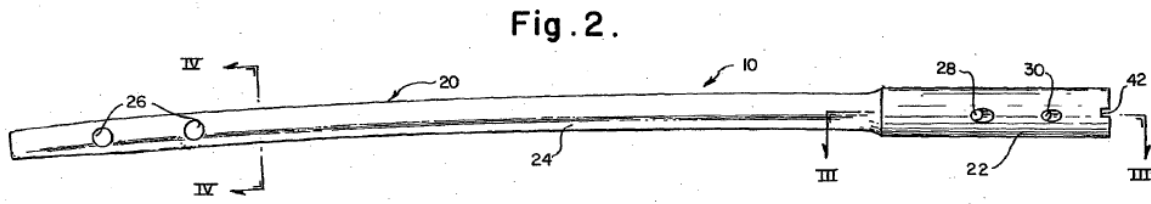


Figure 6 shows that “the lag screw **50** includes a smooth portion **44**, a self-tapping threaded end **46** and a beveled head portion **48**.” Ex. 1002, 20–22. Brumfield teaches that “lag screw **50** is inserted through the distal pair of holes **28** in head **22** of rod **20**.” Ex. 1002, 5:33–35.

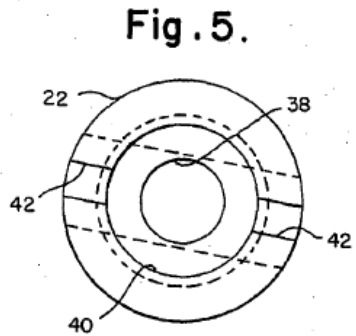
Figure 2 of Brumfield depicts an elevation view of rod **20** shown below:



Intramedullary rod **20** includes a proximal head **22**, a stem **24** distal to the head **22** and a longitudinal bore **32**. . . . the longitudinal axis of rod **20** curves through one plane along the stem **24** to align the rod along the length of the marrow canal of the femur. The head **22** includes at least two pairs of holes, a proximal pair of holes **30** and a distal pair of holes **28**. . . . the holes of a pair are coaxially arranged on a common axis extending through bore **32** in an angled direction relative to the longitudinal axis of rod **20**.

Ex. 1002, 4:29–39.

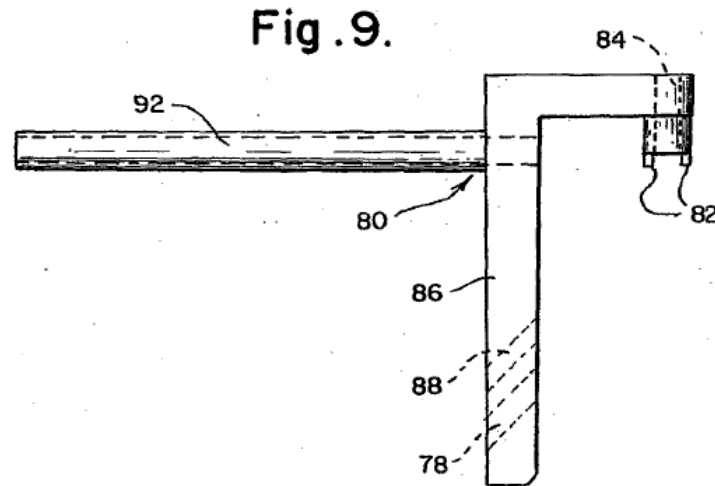
Figure 5 of Brumfield depicts a top end view of rod **20** shown in Figure 2 of Brumfield.



Brumfield teaches that a “threaded counterbore **40** with slots **42** is provided at the end of head **22** to receive the set screw **60** and prongs **82** of tool **80**,

respectively. The axis of slots **42** is parallel in one plane with the common axes of holes **28** and **30** to insure alignment with tool **80**.” Ex. 1002, 47–52.

Brumfield teaches a tool **80** is shown in Figure 9, reproduced below, to help align the parts of femoral fracture device **10** during insertion into a patient’s bone.



Brumfield explains Figure 9 as showing that

tool **80** includes prongs **82** to engage slots **42** of head **22** to align bore **84** with bore **32** for insertion of a (temporary) cannulated locking bolt therethrough to secure tool **80** to rod **20** for driving and for precise alignment of drilling instruments and lag screws. By placing prongs **82** in slots **42**, bores **88** and **78** of arm **86** of tool **80** align with the proximal and distal pairs of holes **30** and **28**, respectively, of head **22**. Lag screw **50** and the optional additional anchoring means can be inserted through the appropriate holes in rod **20** by means of tool **80**.

Ex. 1002, 5:45–55.

In Figure 1, Brumfield shows the rod **20** inserted within a bone with the lag screw **50** coupled at an angle, demonstrating the final disposition of these elements after alignment using tool **80**, as reproduced below:

Fig. 1.

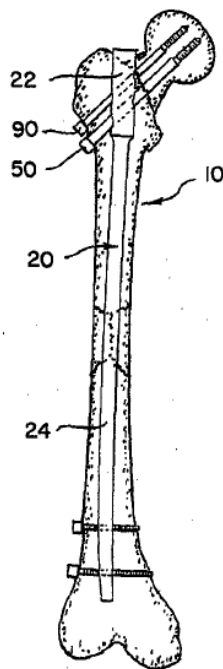


Figure 1 “is a view of the intramedullary rod of the present invention in place in a femur.” Ex. 1002, 5–657.

2. *Marcus (Ex. 1003)*

Marcus is a U.S. patent that teaches “an all-purpose or multi-use femoral intramedullary nail for use in fractures of the femur from the femoral neck to the supracondylar region.” Ex. 1003, 1:6–9. Figure 1 of Marcus depicts “an intramedullary nail according to the invention, within a right femur (shown in phantom lines) and also showing fixation and femoral neck screws insertable into the nail.” Ex. 1003, 4:6–9.

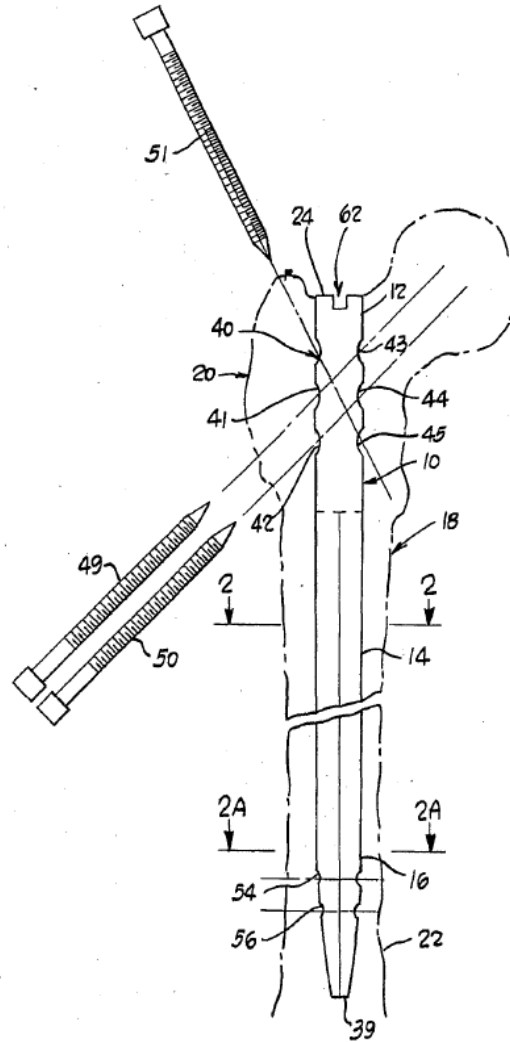


Fig. 1

Figure 1 of Marcus shows

nail **10** is advantageously driven into the femur to a position in which the top end of head **12** is adjacent to and preferably flush with the entry opening formed in the femoral tip. Formed in the sidewall of head **12** are several screw receiving openings **40-45**. . . . opening **40** is diametrically opposed to opening **43**, opening **41** is diametrically opposed to opening **44**, and opening **42** is diametrically opposed to opening **45**. A line **46** extending through the centers of openings **40** and **45** makes an angle A of about 30° with the axis of the nail.

Ex. 1003, 5:32-43. Figure 4 of Marcus depicts top plan view of the head of the nail 10 and is reproduced below:

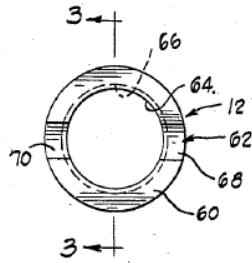


Fig. 4

Figure 4 of Marcus shows that:

Slot **62** has a width somewhat less than the diameter of the opening **64** in head **12**. Opening **64** has internal threads **66** for threadedly securing various tools to the head of the nail both before and after insertion of the nail in the femur. As can be seen at FIG. 4, the slot **62** provides locating grooves **68** and **70** at opposite sides of opening **64**.

Ex. 1003, 6:13–19.

Figure 6 of Marcus depicts “a first jig, in accordance with the invention, for use in drilling and/ or inserting screws in the proximal region of the femur in alignment with openings in an inserted nail.” Ex. 1003,

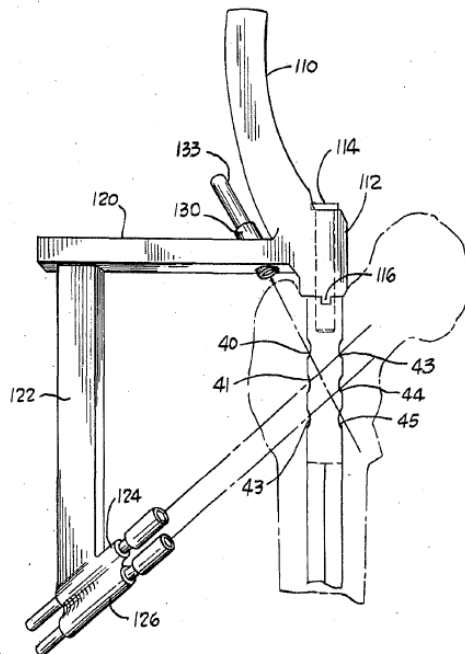


Fig. 6

The jig of Figure 6 above shows a

securing head **112**, the lower end of which has a configuration identical to seat **76** of the driver-extractor. Extending through head **112** is a fastening screw having threads to mate with the internal threads **66** in the head **12** of the nail. The lugs **116** at the bottom of head **112** enter the respective grooves in the upper end of the nail head to accurately align the jig circumferentially as well as axially of the inserted nail, when the screw **114** is fully tightened.

Ex. 1003, 6:64 to 7:4.

3. *Chandran (Ex. 1004)*

Chandran is a U.S. patent that teaches a “surgical rod-and-screw kit is disclosed, for use in ankle arthrodesis. . . . When this screw is tightened, it compresses the lower end of the tibia bone against the talus and/or calcaneum, which improves the stability of the ankle fixation.” Ex. 1003, abstract. Chandran teaches “Figure 4 of Chandran is reproduced below:

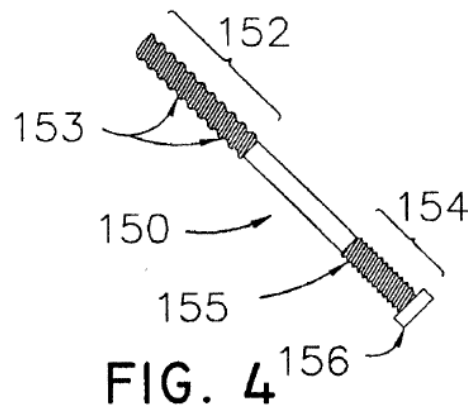


Figure 4 of Chandran, reproduced above, depicts “an oblique screw having a threaded tip that will enter a tibial bone, and a base having optional additional threads with a slightly different pitch which will become set in the calcaneal bone.” Ex. 1004, 4:32–35. Figure 3 of Chandran is a side view of

a vertical rod, having a slanted hole which accommodates the oblique screw shown above and is reproduced below:

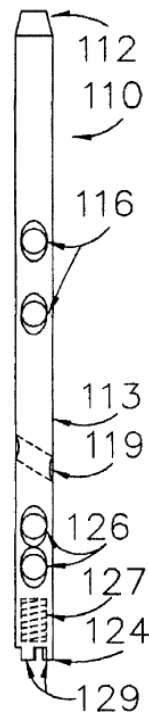


FIG. 3

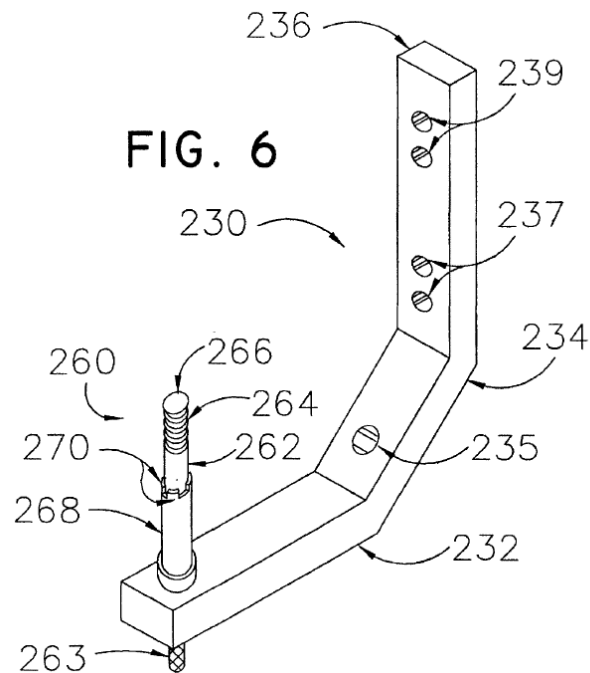
Chandran teaches regarding the rod in Figure 3 above that:

Vertical rod **110** has a tip **112**, a shaft **113**, and a base **124**, with various holes and slots described below. During a surgical operation to insert rod-and-screw assembly **100** into a damaged, diseased, or otherwise defective ankle joint, the tip **112** will be pushed through a hole that has been drilled through the bottom of calcaneal bone **92**, in the heel. This preferably should be done with the aid of a “jig” **230** (also called a guide, template, etc.).

Ex. 1004, 5:15–22. Chandran teaches “the oblique screw **130** [of Figure 4] must pass through an accommodating slanted hole **119** in vertical rod **110** [of Figure 3].” Ex. 1004, 51–53. Chandran also teaches that rod “base **124** is also provided with four slots **129** in a ‘cruciate’ (orthogonal) arrangement . . . When slots **129** interact with alignment fins **270** on the jig coupling bolt,

it allows the alignment jig **230** to be rotated around an axis established by the vertical rod **110**.”

Figure 6 of Chandran, reproduced below, depicts a jig structure that will help a surgeon align several holes that must be drilled through bone surfaces:



Chandran teaches

the jig can be rotated in increments of 90 degrees, so that the alignment fins **270** will reengage the accommodating slots inside the shaft of rod **110**. This will position the oblique arm **234** and vertical arm **236** on the posterior surface of the patient’s heel, and it will cause the hole **235** in oblique arm **234** to be aligned with the oblique hole **119** which passes through vertical rod **110**.

Ex. 1004, 10:30–37. Figure 2 of Chandran is reproduced below:

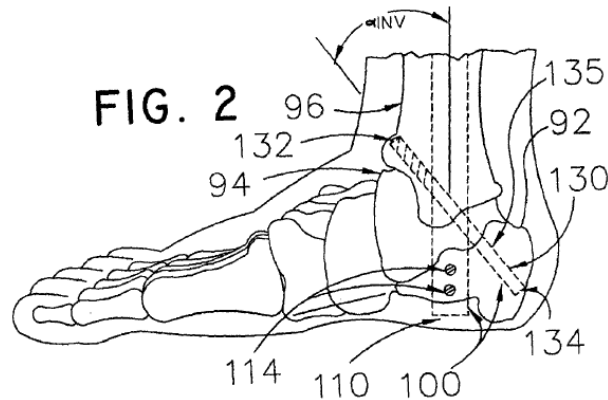


Figure 2 shows “the rod-and-screw assembly of this invention, showing vertical rod and oblique screw inside the major bones of an ankle joint.” Ex. 1004, 25–27.

C. Ground 1: Anticipation over Brumfield

Petitioner contends that claim 59 is anticipated by Brumfield. Pet. 27–37. We note that Patent Owner has not, at this time, provided arguments on the patentability of the challenged claim.

1. Analysis of Claim 59

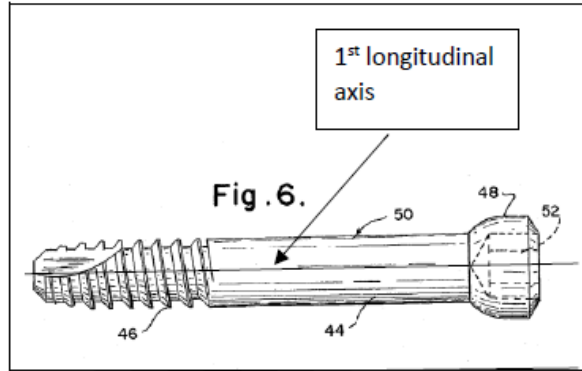
Petitioner asserts, regarding the preamble, that “Brumfield discloses a fixation system for compressing bone. (Ex. 1007 at ¶¶67-70; Ex. 1002 at Figs. 2, 6 and 9).” Pet. 27. Petitioner asserts “Brumfield teaches that ‘[i]f there is a femoral neck fracture the compression of lag screw 50 functions like a compression screw assembly to reduce the fracture.’ (Ex. 1007 at ¶69; Ex. 1002 at 6:57-59).” Pet. 28–29.

Petitioner asserts, as to the recitation in claim 59 of a “first screw member comprising a head portion and a first shaft extending along a first longitudinal axis,” that

Brumfield discloses a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis.

(Ex. 1007 at ¶¶71-74). The first screw member recited in this claim element is lag screw 50 shown in Figure 6. (Ex. 1007 at ¶72; Ex. 1002 at Fig. 6; 5:20-22).

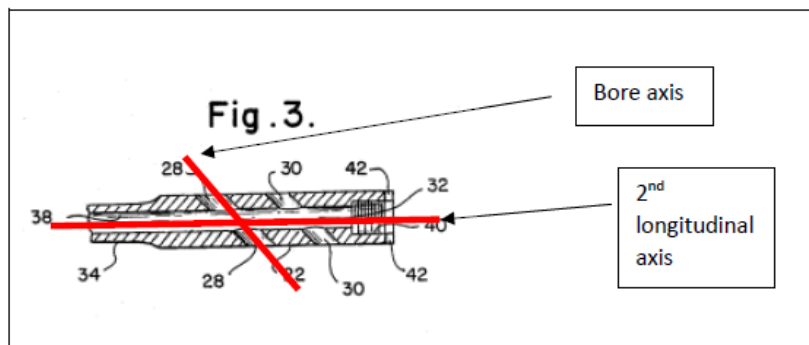
Pet 29. Petitioner provides “annotated Figure 6 of Brumfield showing a first screw member 50 having a head 48, a shaft 44, 46 and a longitudinal axis” that is reproduced below:



Pet. 29. Citing Ex. 1002, figure 6.

Petitioner asserts, as to the recitation in claim 59 of “a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis” that “Brumfield discloses a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through the second shaft along a bore axis. (Ex. 1007 at ¶¶75-80; Ex. 1002 at Figs. 2-3, 4:29-39).” Pet. 30.

Petitioner provides an annotation of Figure 3 of Brumfield, reproduced below:



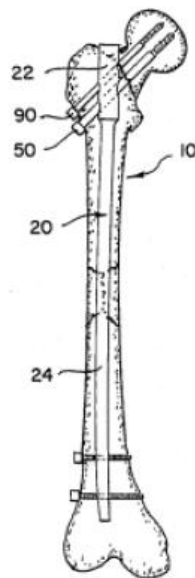
Petitioner asserts annotated figure 3 shows “intramedullary rod 20 including a bore (holes 28, 30) extending through a shaft (22) along a bore axis that extends in an “angled direction relative to the longitudinal axis of rod 20.” (Ex. 1007 at ¶¶77-79; Ex. 1002 at 4:36-39[)].” Pet. 30.

Petitioner asserts, as to the recitation in claim 59 of “an instrument adapted for coupling said first screw member to said second member” that “Brumfield discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶81-85). The instrument recited in this claim element is the tool 80 shown in Figure 9 of Brumfield. (Ex. 1007 at ¶82; Ex. 1002 at Fig. 9; 5:43-55).” Pet. 31.

Petitioner asserts, as to the recitation in claim 59 “wherein said second longitudinal axis and said bore axis define an angle,” that “Brumfield discloses the second longitudinal axis and the bore axis defining an angle. (Ex. 1007 at ¶¶86-89; Ex. 1002 at Fig. 3, 4:36-39).” Pet 32. As shown in the annotated figure 3 reproduced above, Petitioner asserts “Brumfield teaches that ‘[t]he holes of a pair [including holes 28, 30] are coaxially arranged on a common axis extending through bore 32 in an angled direction relative to the longitudinal axis of rod 20.’ (Ex. 1007 at ¶88; Ex. 1002 at 4:36-39[)].” Pet. 32–33.

Petitioner asserts, as to the recitation in claim 59 “wherein said first screw member is adapted for coupling to said second member at said angle” that “Brumfield discloses that the first screw member is adapted for coupling to the second member at the angle. (Ex. 1007 at ¶¶90-93; Ex. 1002 at Fig. 1, 5:50-55).” Pet. 33. Petitioner reproduces figure 1, shown below:

Fig. 1.



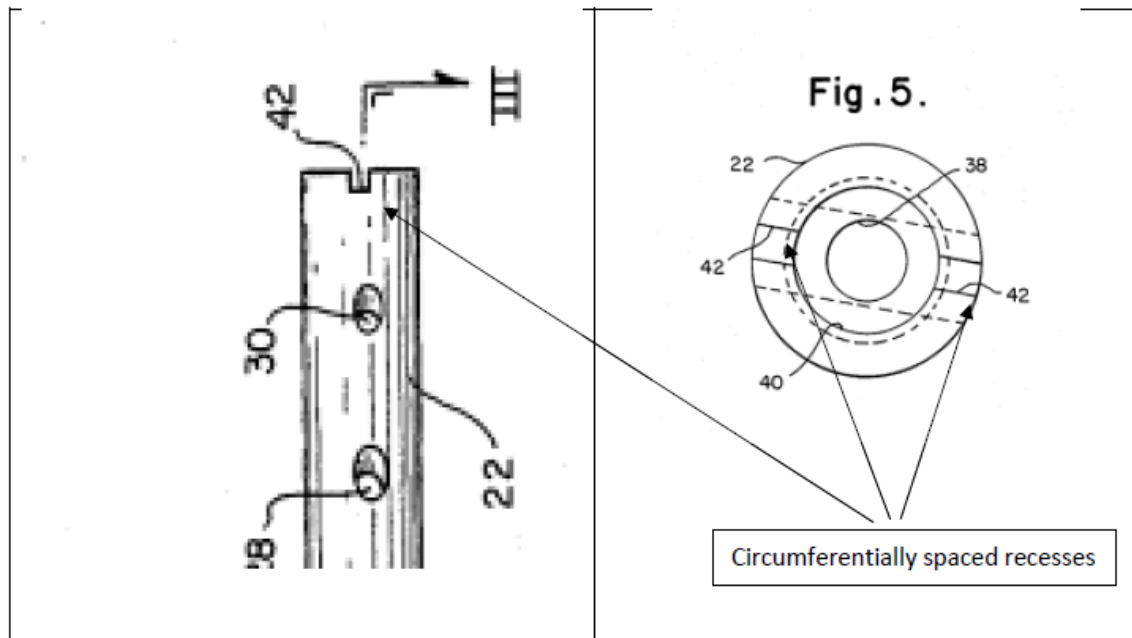
Petitioner asserts “Figure 1 of Brumfield shows lag screw 50 being adapted for coupling to rod 20 at the angle defined by the bore axis through rod 20.” Pet. 33. Petitioner asserts that “Brumfield teaches ‘[l]ag screw 50 and the optional additional anchoring means can be inserted through the appropriate holes in rod 20 by means of tool 80.’ (Ex. 1007 at ¶92; Ex. 1002 at 5:50-55).” Pet. 34.

Petitioner asserts, as to the recitation in claim 59 “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone” that “Brumfield discloses that each of the first screw and the second member is adapted for residing substantially with at least one bone. (Ex. 1007 at ¶¶94-97; at Ex. 1002 at Figs. 1, 3, 5, 4:31-33; 6:28-29, 41-47).” Pet. 34. Petitioner points to Figure 1, shown above, and asserts “Brumfield teaches rod 20 and lag screw 50 being positioned in the femur, including the femoral neck. Ex. 1007 at ¶¶95-96; Ex. 1002 at 4:31-33; 6:28-29, 41-47).” Pet. 35.

Petitioner asserts, as to the recitation in claim 59 “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument” that

Brumfield discloses the second member comprising first and second circumferentially spaced recesses adapted for coupling to the instrument. (Ex. 1007 at ¶¶98-104). The first and second circumferentially spaced recesses recited in this claim element are the slots 42 shown in Figures 2 and 5 of Brumfield. (Ex. 1007 at ¶¶99-102; Ex. 1002 at Figs. 2 and 5, 5:51-54).

Pet. 36. Petitioner reproduces annotated figures 2 and 5 of Brumfield, shown below:



Petitioner asserts

Brumfield teaches that “[t]he tool 80 includes prongs 82 to engage slots 42 of head 22 to align bore 84 with bore 32 for insertion of a (temporary) cannulated locking bolt therethrough to secure to tool 80 to rod 20 for driving and for precise alignment of drilling instruments and lag screws. By placing prongs 82 in slots 42, bores 88 and 78 of arm 86 of tool 80 align with the proximal and distal pairs of holes 30 and 28, respectively of head 22. Lag screw 50 and the optional additional anchoring means

can be inserted through the appropriate holes in rod 20 by means of tool 80.” (Ex. 1007 at ¶103; Ex. 1002 at 5:45-55).

Pet. 36–37.

Based on this preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing that claim 59 was anticipated by Brumfield.

D. Ground 2: Anticipation over Marcus

Petitioner contends that claim 59 is anticipated by Marcus. Pet. 37–50. We note that Patent Owner has not, at this time, provided arguments on the patentability of the challenged claim.

1. *Analysis of Claim 59*

Petitioner asserts, regarding the preamble, that “Petitioner asserts, regarding the preamble, that

to the extent that the portion of the preamble “for compressing bone” of claim 59 is limiting, Marcus discloses the use of an intramedullary nail with angled screws and a jig for use in fractures of the left or right femur. (Ex. 1007 at ¶107; Ex. 1003 at 1:5-9, 2:50-51; 4:59-68, 6:1-7:21).

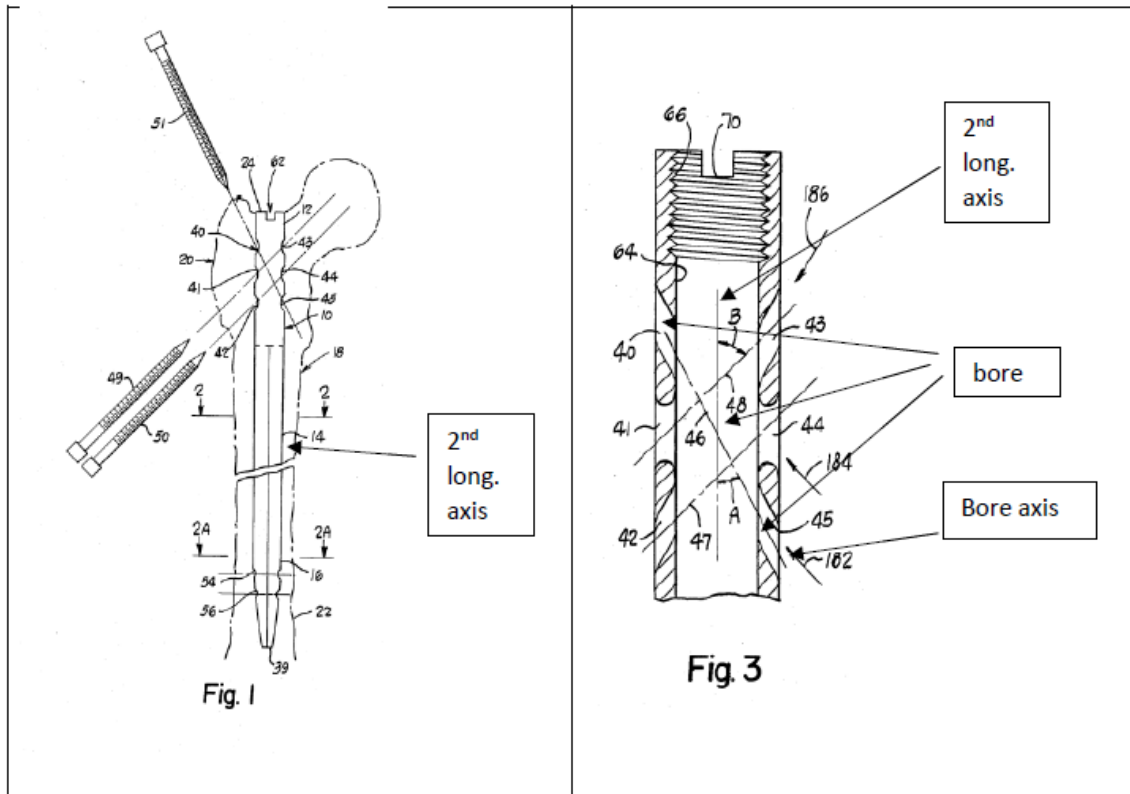
Pet. 38. Petitioner asserts “use of threaded screws to secure bone to bone, by their nature, cause the closing together of bone pieces and thus compression of bone. (Ex. 1007 at ¶108).” Pet. 39.

Petitioner asserts, as to the recitation in claim 59 of a “first screw member comprising a head portion and a first shaft extending along a first longitudinal axis,” that “Marcus discloses a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis. (Ex. 1007 at ¶¶110-112; Ex. 1003 at Fig. 1, 5:48-51).” Pet. 39. Petitioner provides “an annotated portion of Figure 1 of Marcus showing a first screw member 51” that is discussed in the next recitation.

Petitioner asserts, as to the recitation in claim 59 of “a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis” that:

In Marcus, nail 10 is the second member, the “bore” is the hole which is bored or reamed (and thus is made by or as if by boring) that forms openings 40 and 45 during creation of the nail 10, and the “bore axis” is line 46. (Ex. 1007 at ¶¶114-115; Ex. 1003 at Figs. 1 and 3, 4:36-39; 5:51-53, 8:6-9).

Pet. 40. Petitioner provides an annotation of Figures 1 and 3 of Marcus, reproduced below:



Petitioner asserts annotated figure 3 shows “Marcus specifically teaches that the pair of openings 40, 45 are ‘bored (or reamed) along an axis 46 at an angle A which is about 30°’ when the nail is made. (Ex. 1007 at ¶114; Ex. 1003 at 8:6-9).” Pet. 41.

Petitioner asserts, as to the recitation in claim 59 of “an instrument adapted for coupling said first screw member to said second member” that “Marcus discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶119-123).” Pet. 42. Petitioner reproduces figure 6 of Marcus, as shown below:

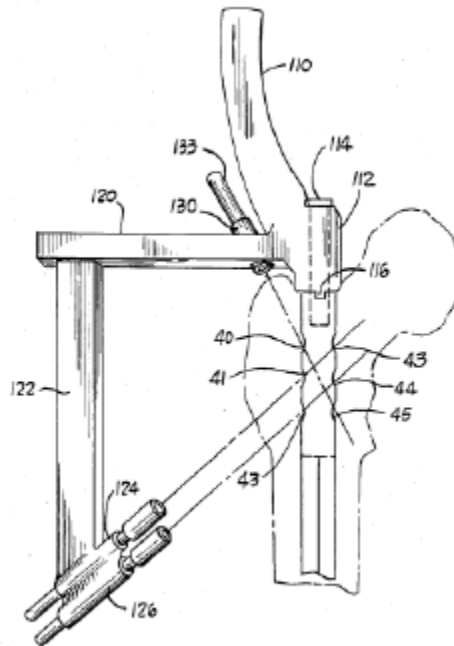


Fig 6

Petitioner asserts

Marcus discloses that the screw guide and drilling jig shown in Figure 6 includes guide sleeve 130 “which is in precise alignment with the centers of openings 40, 45 in the inserted nail, when the jig is secured to the nail. An extension bushing 133 slidable through sleeve 130 can also be provided for more accurate guiding of either a drill for forming the opening of the femur, or for guiding the screw during insertion.” (Ex. 1007 at ¶121; Ex. 1003 at Fig. 6, 7:15-21).

Pet. 42–43.

Petitioner asserts, as to the recitation in claim 59 “wherein said second longitudinal axis and said bore axis define an angle,” that “Marcus discloses

the second longitudinal axis and the bore axis defining an angle. (Ex. 1007 at ¶¶124-127; Ex. 1003 at Fig.3, 5:41-43, 8:6-9, 26-29).” Pet 43. As shown in the annotated figure 3 reproduced above, Petitioner asserts “Figure 3 of Marcus showing the second longitudinal axis of the second member 10 and the bore axis 46 defining an angle A is provided above with annotations. (Ex. 1007 at ¶125; Ex. 1003 at Fig. 3, 8:6-9, 26-29)” Pet. 44.

Petitioner asserts, as to the recitation in claim 59 “wherein said first screw member is adapted for coupling to said second member at said angle” that “Marcus discloses that the first screw member is adapted for coupling to the second member at the angle. (Ex. 1007 at ¶¶128-131; Ex. 1003 at Figs. 1 and 3, 5:51-54, 8:6-9).” Pet. 45. Petitioner asserts, based on Figures 1 and 3 of Marcus reproduced above, that

Marcus also teaches that “[f]or locking the nail in the intertrochanteric region of the right femur a screw, such as screw 51, is inserted downwardly through the openings 40, 45” ... “along axis 46 at an angle A which is about 30°.” (Ex. 1007 at ¶130; Ex. 1003 at Figs. 1 and 3, 5:41-43, 8:6-9, 8:26-29).

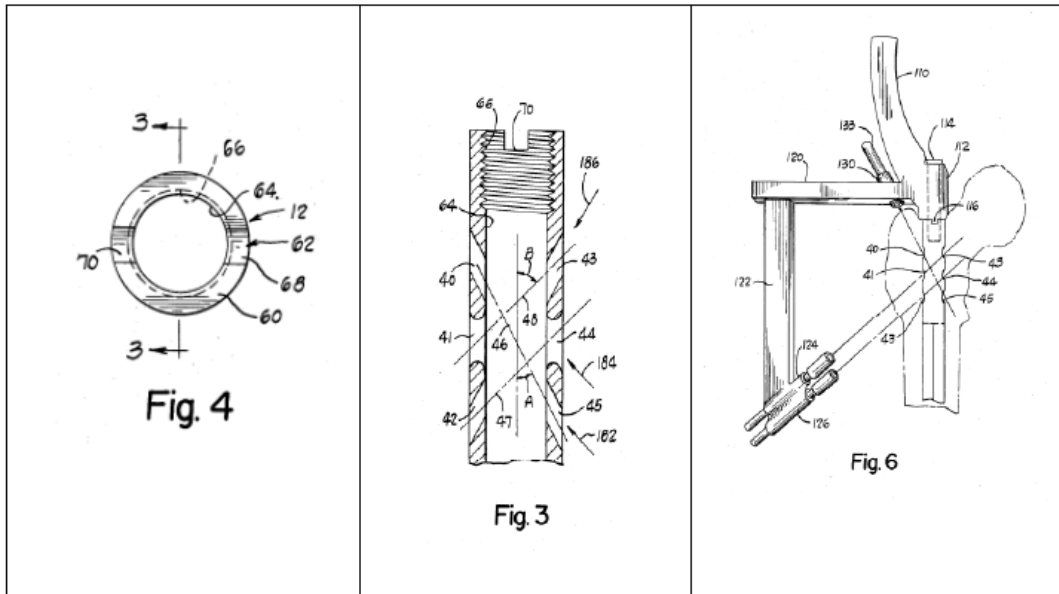
Pet. 46.

Petitioner asserts, as to the recitation in claim 59 “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone” that “Marcus discloses that each of the first screw and the second member is adapted for residing substantially with at least one bone. (Ex. 1007 at ¶¶132-135; Ex. 1003 at Fig. 1, 4:40-44, 5:48-51).” Pet. 47. Petitioner points to Figure 1, shown above, and asserts Marcus teaches “nail 10 being inserted into the medullary canal of a femur to a position in which the nail head 12 is in the intertrochanteric region 20 of the femur and the distal tip 16 is in the distal femur region. (Ex. 1007 at ¶134; Ex. 1003 at 4:40-44).” Pet. 48.

Petitioner asserts, as to the recitation in claim 59 “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument” that

Marcus discloses the second member comprising first and second circumferentially spaced recesses adapted for coupling to the instrument. (Ex. 1007 at ¶¶136-142). The first and second circumferentially spaced recesses recited in this claim element are grooves 62 and 70. (Ex. 1007 at ¶137; Ex. 1003 at Figs. 3, 4 and 6, 6:17-19[)].

Pet. 49. Petitioner points to figures 3, 4, and 6 of Marcus, reproduced below.



Petitioner asserts

Marcus teaches that lugs 116 at the bottom of the head 112 of the screw guide and drilling jig shown in Figure 6 enter the respective grooves 68 and 70 in the upper end of the nail head to accurately align the jig circumferentially as well as axially of the inserted nail. (Ex. 1007 at ¶¶137-141; Ex. 1003 at Fig. 6, 6:68-7:4). In Figure 6 of Marcus, shown above, the instrument 122 is shown as coupled, namely, paired with, the second member (i.e.. nail 10). (Ex. 1007 at ¶141).

Pet. 49–50.

Based on this preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing that claim 59 was anticipated by Marcus.

E. Ground 3: Anticipation over Chandran

Petitioner contends that claim 59 is anticipated by Marcus. Pet. 50–59. We note that Patent Owner has not, at this time, provided arguments on the patentability of the challenged claim.

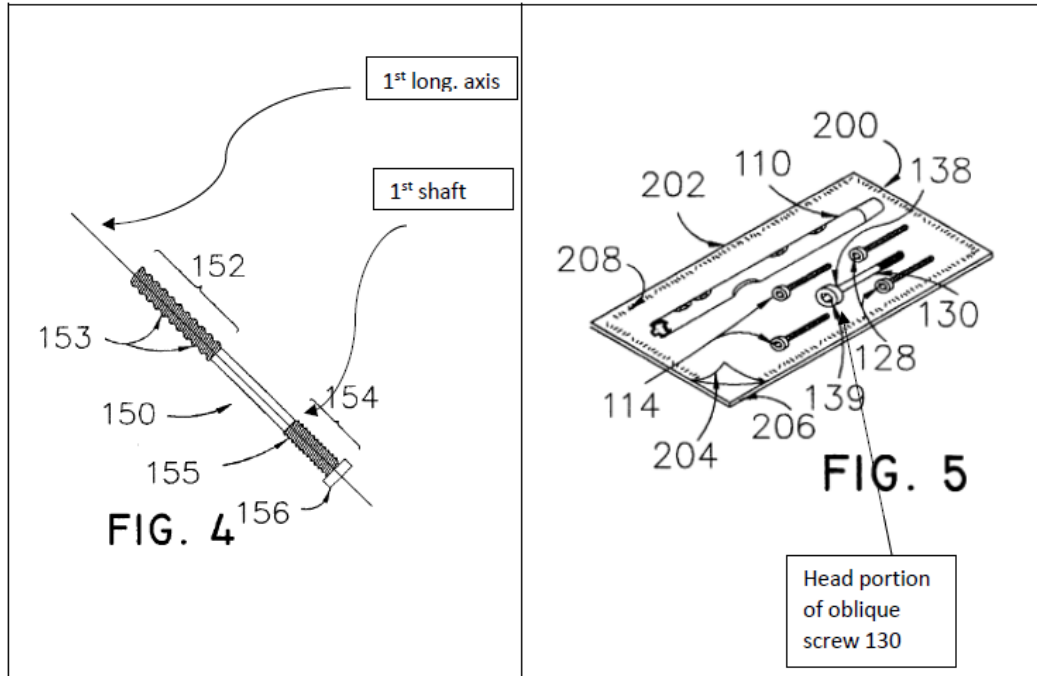
1. *Analysis of Claim 59*

Petitioner asserts, regarding the preamble, that “to the extent that the portion of the preamble ‘for compressing bone’ of claim 59 is limiting, Chandran also teaches that the disclosed fixation assembly may be used for compressing bone. (Ex. 1007 at ¶¶146-148; Ex. 1004 at Abst., 7:24-30, 10:43-48).” Pet. 51.

Petitioner asserts, as to the recitation in claim 59 of a “first screw member comprising a head portion and a first shaft extending along a first longitudinal axis,” that

Chandran discloses a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis. (Ex. 1007 at ¶¶149-153). The first screw member recited in this claim element is oblique screw 130 or 150 illustrated in Figure 4 of Chandran. (Ex. 1007 at ¶150; Ex. 1004 at 7:51-56).

Pet 52. Petitioner provides “annotated Figure 4 of Chandran showing oblique screw 150 (or 130 in Fig. 5) including a head portion 156 and a first shaft extending along a first longitudinal axis” that is reproduced below:

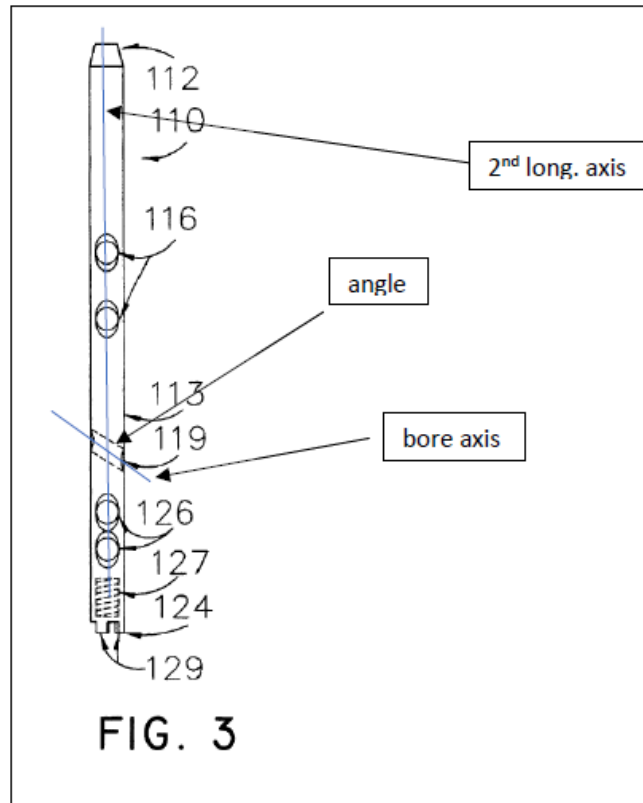


Pet. 52. Citing Ex. 1004, figures 4 and 5.

Petitioner asserts, as to the recitation in claim 59 of “a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis” that

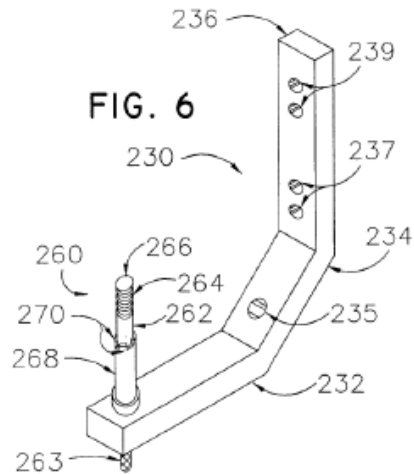
Chandran discloses a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through the second shaft along a bore axis. (Ex. 1007 at ¶¶154-158). The second member recited in this claim element is vertical rod 110. (Ex. 1007 at ¶¶155-156; Ex. 1004 at 5:15-16).

Pet. 52–53. Petitioner provides an annotation of Figure 3 of Chandran, reproduced below:



Petitioner asserts annotated figure 3 shows “Chandran discloses a ‘slanted hole 119’ having a slanted bore axis. (Ex. 1007 at ¶157; Ex. 1004 at Fig. 3).” Pet. 53, 55.

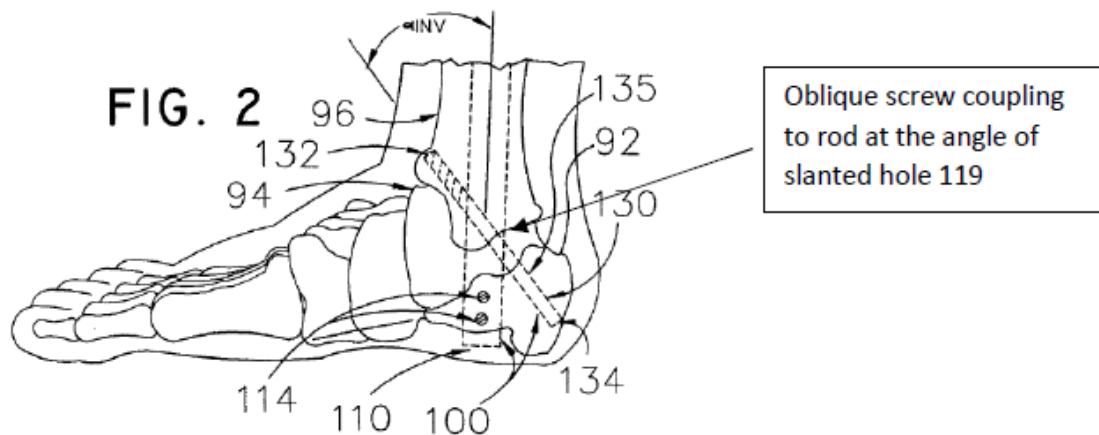
Petitioner asserts, as to the recitation in claim 59 of “an instrument adapted for coupling said first screw member to said second member” that “Chandran discloses an instrument adapted for coupling the first screw member to the second member. (Ex. 1007 at ¶¶159-163; Ex. 1004 at Fig. 6; 9:7-10, 24-40, 49-55).” Pet. 54. Petitioner reproduces figure 6 of Chandran, as shown below:



Petitioner asserts “Chandran teaches the positioning of the jig so that oblique hole 119 is drilled into the patient’s calcaneal bone and then setting and securing the oblique screw. (Ex. 1007 at ¶¶161-162; Ex. 1004 at 10:28-55).” Pet. 54.

Petitioner asserts, as to the recitation in claim 59 “wherein said second longitudinal axis and said bore axis define an angle,” that “Chandran discloses the second longitudinal axis and the bore axis defining an angle. (Ex. 1007 at ¶¶164-166; Ex. 1004 at Fig. 3).” Pet 55. As shown in the annotated figure 3 reproduced above, Petitioner asserts “Chandran teaches a ‘slanted hole 119’ formed in nail 110. (Ex. 1007 at ¶¶165-166; Ex. 1004 at 5:53-54). The axis of this slanted hole 119 is clearly at an angle to the second longitudinal axis.” Pet. 32–33.

Petitioner asserts, as to the recitation in claim 59 “wherein said first screw member is adapted for coupling to said second member at said angle” that “Chandran discloses that the first screw member is adapted for coupling to the second member at the angle. (Ex. 1007 at ¶¶167-171; Ex. 1004 at 6:24-26, 31-35).” Pet. 56. Petitioner reproduces figure 2, shown below:



Petitioner asserts “Figure 2 of Chandran clearly showing oblique screw being adapted for coupling to nail 110 at the angle defined by the bore axis of slanted hole 119 through nail 110.” Pet. 56. Petitioner asserts that “Chandran refers to the first screw member or screw 130 or 150 as ‘oblique’ and defines the term ‘oblique’ to indicate that the screw ‘is positioned at a slanted angle with respect to the main axis of the rod 110.’ (Ex. 1007 at ¶169; Ex. 1004 at 6:24-26).” Pet. 56–57.

Petitioner asserts, as to the recitation in claim 59 “wherein each of said first screw and said second member is adapted for residing substantially within at least one bone” that “Chandran discloses that each of the first screw and the second member is adapted for residing substantially with at least one bone. (Ex. 1007 at ¶¶172-175; Ex. 1004 at 5:16-20, 39-44, 6:20-23).” Pet. 57. Petitioner points to Figure 2, shown above, and asserts Chandran shows “Chandran discloses that each of the first screw and the second member is adapted for residing substantially with at least one bone. (Ex. 1007 at ¶¶172-175; Ex. 1004 at 5:16-20, 39-44, 6:20-23).” Pet. 57.

Petitioner asserts, as to the recitation in claim 59 “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument” that

Chandran discloses the second member comprising first and second circumferentially spaced recesses adapted for coupling to the instrument. (Ex. 1007 at ¶¶176-181). The first and second circumferentially spaced recesses recited in this claim element are the slots 129 illustrated in Figure 3 of Chandran. (Ex. 1007 at ¶177; Ex. 1004 at 6:2-10).

Pet. 58. Petitioner points to figure 3 of Chandran, reproduced above.

Petitioner asserts

Chandran teaches that slots 129 “will accommodate alignment fins 270 [of jig 230].” (Ex. 1007 at ¶179; Ex. 1004 at 6:2-10). Chandran also teaches that “[w]hen the slots interact with alignment fins 270 on the jig coupling bolt, it allows the alignment jig 230 to be rotated around an axis established by vertical rod 110, after the rod has been inserted into the tibial bone.” (Ex. 1007 at ¶180; Ex. 1004 at 6:2-10).

Pet. 59.

Based on this preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing that claim 59 was anticipated by Chandran.

XI. CONCLUSION

Petitioner has, at this stage, established a reasonable likelihood of prevailing in showing that at least one of the challenged claims is unpatentable. This determination is, however, based on a preliminary record and is not final on any issues of patentability. We will make a final determination on the patentability of the challenged claims, as necessary and applying the preponderance of the evidence standard, based on a fully developed record through trial.

XII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a) an *inter partes* review of claim 59 of the '802 patent is hereby *instituted* on the grounds set forth in the Petition, commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial will be conducted in accordance with a separately issued Scheduling Order.

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